APR 1 1 2014

510(k) SUMMARY
Inion FreedomPin™

Manufacturer and submitter:	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Date:	December 16, 2013
Contact person	Kati Marttinen, Quality and Regulatory Director Phone: +358 10 830 6600 Fax: +358 10 830 6691 kati.marttinen@inion.com
Establishment registration number	9710629
Trade name of the device	Inion FreedomPin™
Device classification and product code	Class II Classification Panel: Orthopaedic Product Code: HTY Common name: Bone fixation pin Regulation number: 888.3040
Predicate device	Inion OTPS Biodegradable Pin (K050275)
Conformance with performance standards	Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

The Inion FreedomPin™ products are intended to maintain accurate alignment of fragments of fractured bone in the presence of appropriate immobilization.

The INION FreedomPin™ products are made of degradable co-polymers composed of L-lactic acid and D-lactic acid. These polymers have a long history of safe medical use and they degrade in vivo by hydrolysis into alpha-hydroxy acids that are metabolised by the body. The pins are dyed green for better visualization during the surgical procedure by a minimal amount of Drug and Cosmetic (D&C) Green No. 6, which is used in several biodegradable sutures and implants.

Inion FreedomPins have nominal dimensions ranging from 1.5 – 3.2 mm in diameter and 30 – 70 mm in length. In addition, sterile Pin Kits are offered which contain 2-3 pins and the required sterile, single use instruments needed for the insertion. The implants retain sufficient strength to fulfil their intended function during the healing period of the fracture or osteotomy, and degrade gradually thereafter. Bioresorption takes place within two to four years. The implants are provided sterile to the user and are not to be resterilized.

Inion FreedomPins provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.

Inion FreedomPins are designed to be used with customized instrumentation consisting of drill bits, K-wires, applicators, and arthroscopic pistons and tips.

Indications for use

The Inion FreedomPin™ products are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Performance testing for substantial equivalence determination

Mechanical testing in shear, bending, pull-out and torsion was performed to verify the strength and fixation properties of Inion FreedomPin™ and to compare them to the predicate devices. Testing was conducted initially and during *in vitro* degradation.

In vitro degradation testing was carried out to determine the degradation profile (i.e., change in material and mechanical properties) and verify the sufficiency of the mechanical stability over healing period as the polymer degrades during *in vitro* degradation and to ensure the degradation of the Inion FreedomPin™.

Functional and handling test and simulated clinical use test were performed to verify that the implants, accessory instruments, packaging and instructions for use are functioning together as intended, and conform to the defined user needs and intended uses.

The data demonstrates that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion FreedomPin™ are substantially equivalent with the predicate device Inion OTPS Biodegradable Pin (K050275). The devices have passed the tests for functionality and handling in simulated clinical use settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Inion Oy
Ms. Kati Marttinen
Quality and Regulatory Director
Lääkärinkatu 2
FIN-33520 Tampere
Finland

Re: K133932
Trade/Device Name: Inion FreedomPin™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: March 3, 2014
Received: March 6, 2014

Dear Ms. Marttinen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133932

Statement of Indications for Use

510(k) Number: K133932

Device Name: Inion FreedomPin™

The **INION FreedomPin™** products are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth FDA Frank -S

Division of Orthopedic Devices